United States Department of Agriculture Animal and Plant Health Inspection Service Center for Veterinary Biologics P. O. Box 844 Ames, IA 50010

1. Reagent Name: Leptospira pomona Master Reference Bacterin

2. Strain or Source: N/A

3. Lot Number: IRP 524 (05)

4. Fill Date: June 15, 2005

5. Expiration Date: The stability of this reagent will be evaluated over time by the CVB using hamster PD_{50} values. Any changes in use dilutions will be communicated via CVB Notice.

Precautions: There are no known hazards associated with the use of this reagent.

- **6. Intended Use:** To be used as a reference bacterin in accordance with **SAM 624** (Supplemental Assay Method for *in vitro* Potency Testing of *Leptospira interrogans* Serovar *pomona* Bacterins). **CAUTION:** This reference is to be used for canine, swine, and bovine vaccines as approved in Outlines of Production.
- 7. Instructions for Use: Reconstitute lyophilized bacterin with 1.0 mL of sterile water. Adjust final dilution (using 0.85% NaCl solution) based on host animal dosage per the following table. The final dilution is considered as UNDILUTED when entering data into the RelPot software program.

Host	Use
dose	Dilution
1 mL	1:20
2 mL	1:40
4 mL	1:80
5 mL	1:100

- **8. Test of Reagent:** Tested satisfactory for sterility according to 9 CFR 113.26. Host animal (canine and porcine) studies conducted by Dr. Carole Bolin at Michigan State University. Data summary available upon request.
- **9. Container Size, Type, Weight, or Volume:** 2-mL serum vials (lyophilized)

10. Storage Conditions: 2° - 7° C

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- **11. CVB Technical Contact:** Bacteriology Section, Center for Veterinary Biologics, (515) 337-6140 or FAX (515) 337-7673.
- 12. Origin and Passage History: Passage history not available.
- **13. Method of Preparation:** This non-adjuvanted bacterin was produced by a licensee according to a confidential outline of production.
- **14. Other:** None.

Reagent orders and feedback should be sent *including phone number* to the following email address: CVB@aphis.usda.gov

Reagent orders forms (APHIS 2018) are available from: http://www.aphis.usda.gov/animalhealth/cvb_forms

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